

**UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS**

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<p>KERRY LANGSTAFF, <u>ET AL.</u>, Petitioners, vs. ALLEN A. MITCHELL, M.D., SAMUEL M. LESKO, M.D., and TRUSTEES OF BOSTON UNIVERSITY, Respondents.</p>	<p>) Civil Action No. 04-mc-10137-WGY ) ) ) ) ) ) ) ) ) ) ) ) )</p> <p><b>Related Civil Action:</b> United States District Court for the Northern District of California, San Jose Division, Civil Action No. 03-CV-01116-HRL KERRY LANGSTAFF and BRADSHAW LANGSTAFF, Individually, and on Behalf of KAITLYN SIERRA LANGSTAFF, a minor child, vs. MCNEIL CONSUMER &amp; SPECIALTY PHARMACEUTICALS, a Division of MCNEIL-PPC, INC.; and JOHNSON &amp; JOHNSON.</p>
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**RESPONDENTS' OPPOSITION TO  
PETITIONERS' MOTION TO COMPEL  
THE CUSTODIAN OF RECORDS FOR DR. ALLEN A. MITCHELL AND  
THE CUSTODIAN OF RECORDS FOR SLONE EPIDEMIOLOGY CENTER  
TO COMPLY WITH SUBPOENAS DUCES TECUM**

Respondents Allen A. Mitchell, Samuel M. Lesko, and Trustees of Boston University (hereinafter “Respondents”) submit the following opposition to Petitioners’ Motion to Compel the Custodian of Records for Dr. Allen A. Mitchell and the Custodian of Records for Slone Epidemiology Center to Comply with Subpoenas Duces Tecum (“Motion to Compel”).

Respondents will agree to provide documents presented to the FDA (Request number 4), as well as copies of all published articles resulting from the Boston University Fever Study (Request number 8) and final minutes from meetings of the Advisory Committee (Request numbers 9 and 25). However, Petitioners’ Motion to Compel the remaining documents should be denied. The documents Petitioners seek concern (a) confidential business dealings between

Boston University (or Boston University researchers) and McNeil Consumer & Specialty Pharmaceuticals (“McNeil”) (Request numbers 10, 12, and 19) or (b) information about doctors who enrolled patients in the Boston University Fever Study (Request number 17) or the requests are overbroad (Request numbers 10, 18, 19). Petitioners have failed to justify this fishing expedition for information that bears no relevance to the underlying action, and therefore this motion should be denied.

#### BACKGROUND

Slane Epidemiology Center is a public health research center at Boston University that focuses on studying the possible health effects of medications and a wide variety of other factors in adults and children. The Center is directed by Dr. Allen Mitchell. Between February of 1991 and June of 1993, Dr. Mitchell, together with Dr. Samuel Lesko, conducted a randomized double-blind office-based clinical trial among children with fevers to assess the risks of rare but serious adverse events following the use of pediatric ibuprofen. Pediatric ibuprofen has been available by prescription since 1989, but in 1991 had not yet been approved for over-the-counter use. This study, which was supported by McNeil Consumer Products Company,<sup>1</sup> one of the manufacturers of pediatric ibuprofen, was designed to gather additional safety data on pediatric ibuprofen, with the goal of seeking approval through the U.S. Food and Drug Administration (“FDA”) for over-the-counter use. The control for the study was the drug acetaminophen, which was the drug of choice for the treatment of fever in children, and which had been available over-the-counter for some time.

A total of 1,735 physicians enrolled their patients in the study. The study subjects were children between six months and twelve years of age who were seen by the physicians for an

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<sup>1</sup> The present name of the company is “McNeil Consumer & Specialty Pharmaceuticals.”

acute febrile illness and who met other specified criteria for enrollment. A total of 84,192 children participated in the study, and these children were randomly assigned to receive acetaminophen or ibuprofen. The hypothesis being tested was whether ibuprofen increases (relative to acetaminophen) the risk of hospitalization for gastrointestinal bleeding, renal failure, anaphylaxis, or Reye's Syndrome. Information was gathered by means of a questionnaire that was sent to the parent or guardian of each participant and that asked, among other things, about the occurrence of any serious medical events in the four weeks following enrollment that required a visit to an emergency department, physician's office, or hospitalization.

Drs. Mitchell and Lesko concluded that the risk of hospitalization for gastrointestinal bleeding, renal failure, anaphylaxis, or Reye's Syndrome was not increased following short-term use of ibuprofen in children. They did not opine on the risks of less severe outcomes or the risks of prolonged ibuprofen use. The study has become known as the "Boston University Fever Study."

All study data gathered by Drs. Mitchell and Lesko was provided to McNeil, which in turn submitted both the results of the study and all of the underlying data to the FDA. Drs. Mitchell and Lesko's findings were also published in several articles. See, for example, Lesko SM, Mitchell AA. An assessment of the safety of pediatric ibuprofen: a practitioner-based randomized clinical trial. JAMA. 1995; 273: 929-933. The FDA ultimately approved McNeil's pediatric ibuprofen (marketed as Children's Motrin) for over-the-counter use.

#### UNDERLYING LAWSUIT

On March 14, 2003, Kerry Langstaff, et al. ("Langstaff Plaintiffs"), brought a products liability suit against McNeil Consumer & Specialty Pharmaceuticals alleging that Kaitlyn Langstaff, a minor child, developed Stevens Johnson Syndrome ("SJS") and toxic epidermal

necrolysis (“TEN”) because of a reaction to Children’s Motrin. Both SJS and TEN are serious dermatological disorders.

On November 4, 2003, Langstaff Plaintiffs served upon the Custodian of Records for Slone and the Custodian of Records for Dr. Allen Mitchell a subpoena duces tecum seeking 25 categories of documents, including voluminous clinical trials data in paper and electronic form generated by the Boston University Fever Study. See Petitioners’ Exhibit A. On November 19, 2003, Respondents provided Langstaff Plaintiffs with 17 pages of written objections to the inspection or copying of the designated materials pursuant to Fed. R. Civ. P. 45(c)(2)(B). See Petitioners’ Exhibit B. For the next four months, Langstaff Plaintiffs did not contact Respondents or otherwise take any action to obtain the documents set forth in the subpoenas. Instead, on April 9, 2004, and April 26, 2004, Langstaff Plaintiffs served deposition subpoenas and subpoenas duces tecum upon Drs. Samuel Lesko and Allen Mitchell, requesting Drs. Mitchell and Lesko to produce a subset of the same documents to which Respondents had previously objected. These April subpoenas are the subject of a separate motion to quash, filed by Drs. Mitchell and Lesko on April 28, 2004, in the U.S. Court for the District of Massachusetts. The Motion to Quash is presently assigned to Judge O’Toole. See Mitchell, et. al. vs. Langstaff, et. al, No. 04-10128-GAO.

## ARGUMENT

### I. RESPONDENTS HAVE NOT WAIVED THEIR OBJECTIONS TO THESE SUBPOENAS.

Langstaff Plaintiffs argue that Respondents have waived all objections to the subpoenas at issue because Respondents’ initial objections, which were served pursuant to Fed. R. Civ. P. 45(c)(2)(B), were due on Tuesday, November 18, 2003, but were not served until the following

day—Wednesday, November 19, 2003. Although the objections were served one day outside of the 14 day period set forth in Rule 45(c), Respondents respectfully request this Court to find that Respondents have not waived their objections because the one-day delay resulted in no prejudice to Petitioners and because this case falls within the well-established “good cause” exception to the 14-day rule. Courts have held that “in unusual circumstances and for good cause, the failure to act timely will not bar consideration of objections.” Concord Boat Corp. et al. v. Brunswick Corp., 169 F.R.D. 44, 48 (S.D.N.Y. 1996). “Courts find such unusual circumstances where: (1) the subpoena is overbroad on its face and exceeds the bounds of fair discovery, (2) the subpoenaed witness is a non-party acting in good faith, and (3) counsel for witness and counsel for subpoenaing party were in contact concerning the witness’ compliance prior to the time the witness challenged legal basis for the subpoena.” Id. (citations omitted). See also, Semtek Int’l, Inc. v. Merkuriy Ltd., 1996 WL 238583 at 2 (N.D.N.Y. 1996).

All three circumstances exist in the instant case. The original subpoenas, which contained 25 separate categories of document requests, called for production of numerous electronic databases and over one hundred thousand pages of documents. They clearly exceeded the bounds of fair discovery for all of the reasons set forth in Respondents’ 17-page objection letter, which Respondents served on Petitioners on November 19, 2003. See Petitioners’ Exhibits A & B. Second, Dr. Mitchell and Slone Epidemiology Center are non-parties to the underlying products liability litigation. Third, Petitioners were well aware, prior to November 19, 2003, that Respondents would be objecting to the subpoenas, as Dr. Mitchell and Slone had already filed objections to an identical document request served on them in July 2003 by counsel for Petitioners in connection with a separate products liability case against Wyeth

Pharmaceuticals.<sup>2</sup> As set forth in undersigned counsel's attached affidavit, Petitioners' counsel's office contacted Respondents' counsel before receiving Respondent's objections on November 19, 2003, to state that Petitioners assumed the University would be objecting to the subpoenas and that, if the objections couldn't be worked out, they would be filing a motion to compel. For all of these reasons, a strict application of Rule 45(c)(2)(B) is not warranted here, and this Court should find that Respondents' one-day delay in filing their objections does not result in Respondents' waiver of its right to oppose Langstaff Plaintiffs' Motion to Compel.

II. RESPONDENTS SHOULD NOT BE REQUIRED TO PRODUCE THE DOCUMENTS REQUESTED BECAUSE PETITIONERS HAVE NOT DEMONSTRATED THAT THE REQUESTS ARE RELEVANT TO THE UNDERLYING LAWSUIT, THE REQUESTS ARE OVERBROAD, AND THE REQUESTS REQUIRE DISCLOSURE OF CONFIDENTIAL FINANCIAL INFORMATION.

While Federal Rule of Civil Procedure 45 allows for discovery from non-parties, Section (c)(2)(B) of that rule, as well as rule 26(c), allows the Court to protect any person who is not a party from "annoyance, embarrassment, oppression, or undue burden and expense." In addition, Rule 26(c) provides that the court may insure that "confidential . . . commercial . . . information not be revealed or be revealed only in a designated way." Non-party status is a factor to be considered when determining the burden imposed by compliance with a subpoena and "[d]iscovery may be denied when, in the court's judgment, the inquiry lies in a speculative nature." Allen v. Howmedica Leibinger, 190 F.R.D. 518, 522 (W.D. Tenn. 1999); see also Katz v. Batavia Marine, 984 F.2d 422, 424 (Fed. Cir. 1993).

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<sup>2</sup> On July 23, 2003, the Custodian of Records for Slone Epidemiology Center and the Custodian of Records for Allen Mitchell received identical subpoenas duces tecum in connection with the case Madden, et al. v. Wyeth, et al., Civil Action No. 3-03-CV-0167R, United States District Court for the Northern District of Texas. The Madden plaintiffs are represented by James Barber, who is also counsel for Langstaff Plaintiffs. On August 5, 2003, Respondents served Rule 45(c)(2)(B) objections upon Attorney Barber in connection with the subpoenas issued in the Madden case.

Once a non-party objects to discovery, “the burden shifts to the party seeking the information to demonstrate that the requests are relevant to the subject matter involved in the pending action. . . . The party seeking discovery must be able to articulate the possible linkage between the discovery sought and admissible evidence.” Allen v. Howmedica Leibinger, 190 F.R.D. at 522 (citation omitted); Andritz Sprout-Bauer v. Beazer East, 174 F.R.D. 609, 631 (M.D. Pa. 1997).

Petitioners’ Motion to Compel does not articulate a justification for the particular documents requested. Instead, Petitioners rely on the conclusory assertion that their requests involve “crucial documents, which go to the heart of Petitioners’ suit against McNeil.” As Petitioners have not met their burden of articulating the relevancy of their requests to their case against McNeil, and their inquiry is speculative in nature, their motion should be denied.

Heidelberg Americas, Inc. v. Tokyo Kikai Seisakusho Ltd., 333 F.3d 38 (1st Cir. 2003).

For example, Request numbers 10, 12, and 19 seek information about general financial transactions between Boston University and McNeil over the past ten years as well as specific financial information (such as checks and 1099 forms) provided by McNeil to Drs. Mitchell and Lesko. First, Petitioners have made no showing that they are unable to obtain this financial information from McNeil, which has agreed to produce records of payments made to Boston University and Drs. Mitchell and Lesko. (See Exhibit D to Petitioner’s Motion.) Boston University does not keep systematic records on a University-wide basis of payments received from a particular private entity such as McNeil. To require it to search for such records would be unduly burdensome. Second, Petitioners have not articulated any theory of their case pursuant to which the amount of money that McNeil may have paid to Boston University in connection with research performed by any one of its 8,000 employees or paid to Drs. Mitchell or Lesko is in any

way relevant to their products liability claim against McNeil. Petitioners have not put forward one scintilla of evidence suggesting that such payments had any bearing whatsoever on the methodology of the Boston University Fever Study or the legitimacy of the study results. Absent such evidence, Petitioners should not be allowed to go on a fishing expedition that will require disclosure of business dealings of the University or disclosure of Drs. Mitchell and Lesko's private financial records.

Plaintiffs have also failed to articulate any basis for Request number 17, which is "a list of all 1700 physicians who participated in the Boston Fever Study along with their addresses and phone numbers." Information regarding the identities of and contact information for these physicians is wholly irrelevant to Petitioners' claims.

Likewise, there is no basis to require Respondents to produce "printouts of every e-mail" (Request number 18) between the researchers and McNeil absent a showing by Petitioners that such communications are relevant to the injuries of Kaitlyn Langstaff.

Finally, while Respondents will provide minutes from the Boston University Fever Study Advisory Committee, Respondents do not agree to provide "unpublished documents" (Request number 25) relating to the Advisory Committee absent any showing of how these documents are relevant to the underlying action.

Respondents' responses to the particular requests set forth in Petitioners' Motion to Compel are as follows:

**Request No. 4:**

All presentations, slides, lectures or related documents that were presented to the FDA on behalf of McNeil Consumer Healthcare or Wyeth Consumer Healthcare regarding ibuprofen.

**Response to Request No. 4:**

Respondents will produce documents in their custody and control that were presented to the FDA on behalf of McNeil Consumer Healthcare regarding ibuprofen. Respondents did not have any involvement in Wyeth's request for or receipt of FDA approval to market non-prescription pediatric ibuprofen.

**Request No. 8:**

Copies of all research studies, including drafts of or final manuscripts sponsored by McNeil Consumer Healthcare or Wyeth Consumer Healthcare, whether published in peer-reviewed journals or unpublished studies, on the subjects of adverse skin reactions by adults or children from ibuprofen; SJS or TEN caused by or associated with ibuprofen; renal toxicity of ibuprofen; gender differences of adverse reactions to ibuprofen.

**Response to Request No. 8:**

Respondents will provide the published articles resulting from studies supported by McNeil or Wyeth which contain discussion of the topics listed. Langstaff Plaintiffs have made no showing as to why they need drafts of such manuscripts and the request for drafts contravenes Rule 45(c)(3)(B) by seeking disclosure of unpublished reports that represent an unretained expert's opinion.

**Request No. 9:**

All drug safety committee, data and monitoring committee or other committee reports in the Boston Fever Study that reviewed the safety of ibuprofen that discuss any adverse event or reaction associated with ibuprofen, including but not limited to: skin conditions, such as rash, erythema multiforme, SJS, TEN, or renal failure.

**Response to Request No. 9:**

Respondents will provide copies of final minutes from meetings of the Advisory Committee to the Boston University Fever Study.

**Request No. 10:**

All contracts or agreements for the employment of Boston University or Boston University Medical Center or Sloane Epidemiology Unit, School of Public Health, Boston University School of Medicine to conduct the clinical trial that was known as the Boston Fever Study, including all correspondence, contracts, memorandums, agreements, payments, reports or other documents that dealt with the Boston Fever Study.

**Response to Request No. 10:**

Respondents object to this request on the grounds that it is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence. Respondents further object to the extent that such documents contain attorney-client privileged information. Langstaff Plaintiffs have made no showing that the contracts, communications, and business dealings between Boston University and McNeil have any relevance to this lawsuit, and Langstaff Plaintiffs have no reasonable basis for seeking such documents.

**Request No. 12:**

All agreements, contracts, consulting agreements, proof of payments, 1099 forms, checks, or documents between Samuel Lesko, M.D. or Allen A. Mitchell, M.D., and McNeil Consumer Healthcare or Wyeth Consumer Healthcare or Johnson & Johnson that reflect payment as a clinical investigator in the Boston Fever Study.

**Response to Request No. 12:**

Drs. Mitchell and Lesko have not been retained as experts for McNeil. As such, they are not required pursuant to Rule 26(a)(2)(B) to disclose “compensation to be paid for the study and testimony.” The financial information sought by Langstaff Plaintiffs is confidential, and Plaintiffs have made no showing that business dealings between Drs. Mitchell and Lesko and McNeil have any relevance to this lawsuit. Langstaff Plaintiffs have no reasonable basis for seeking such documents other than to harass Drs. Mitchell and Lesko. Langstaff Plaintiffs should not be allowed to go on this fishing expedition without making a strong showing of relevance sufficient to outweigh the substantial intrusion on the personal privacy of Drs. Mitchell

and Lesko and intrusion into confidential business arrangements of Boston University. Slone did not undertake the Boston University Fever Study on behalf of Wyeth Consumer Healthcare.

**Request No. 17:**

A list of all 1700 physicians who participated in the Boston Fever Study along with their addresses and phone numbers.

**Response to Request No. 17:**

Respondents strongly object to this request on the grounds that it is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence. Langstaff Plaintiffs can have no conceivable basis for requesting the contact information for the doctors participating in the study. Respondents further strongly object to this request to the extent that Langstaff Plaintiffs wish to secure this information in order to contact the physicians who engaged in the Study. Many of these doctors are currently participating in ongoing studies conducted by Slone for various federal agencies. The physicians' cooperation in such research studies will be chilled or curtailed if, as a consequence of participation, physicians are contacted by plaintiffs' attorneys seeking to verify information obtained from researchers. Such physicians might also knowingly or unknowingly provide information that would allow Langstaff Plaintiffs to identify particular patients.

**Request No. 18:**

All printouts of every e-mail between Samuel Lesko, M.D. or Allen Mitchell, M.D. or the Slone Epidemiology Unit of Boston University and McNeil Consumer Healthcare or Wyeth Consumer Healthcare or their agents, employees or designated representatives concerning the evaluation of the safety and efficacy of ibuprofen in children.

**Response to Request No. 18:**

Respondents object to this request on the grounds that it is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence. Langstaff Plaintiffs cannot demonstrate that e-mails between Drs. Lesko and Mitchell and McNeil or Slone

employees and McNeil have any relevance to their claims. Again, Langstaff Plaintiffs should not be allowed to go on this fishing expedition without making a strong showing of relevance sufficient to outweigh the substantial intrusion on the personal privacy of Drs. Mitchell and Lesko and the intrusion into confidential business arrangements of Boston University. Slone did not undertake the Boston University Fever Study on behalf of Wyeth Consumer Healthcare, and Langstaff Plaintiffs' request for information relating to Wyeth bears no relevance to this case.

**Request No. 19:**

Any and all documents that detail the financial support, grants, donations, or money paid to the Slone Epidemiology Unit, Boston University School of Medicine or its affiliated institutions, or Boston University by McNeil Consumer Healthcare or Wyeth Consumer Healthcare for the last 10 years.

**Response to Request No. 19:**

Respondents object to this request on the grounds that it is irrelevant, overbroad, and not reasonably calculated to lead to the discovery of admissible evidence. Langstaff Plaintiffs can make no showing that the general financial transactions of Boston University (which has approximately 8,000 employees) with McNeil Consumer Healthcare over the last ten years have any relevance to the injuries experienced by Kaitlyn Langstaff. As Wyeth is not a party to the instant lawsuit, Langstaff Plaintiffs' request for information relating to Wyeth has no relevance to this case.

**Request No. 23**

All expert reports generated by Dr. Samuel Lesko, Dr. Allen Mitchell or any staff member of Boston University for McNeil Consumer Healthcare or Wyeth Consumer Healthcare regarding ibuprofen.

**Response to Request No. 23:**

Neither Dr. Mitchell nor Dr. Lesko has been retained as an expert by McNeil. As such, Langstaff Plaintiffs have no right, under Fed. R. Civ. P. 26(a)(2)(B) to any expert reports.

Notwithstanding this objection, assuming that “expert reports” refers to reports prepared pursuant to Fed. R. Civ. P. 26(a)(2)(B), Drs. Lesko and Mitchell have not produced any expert reports.

**Request No. 25:**

All minutes of meetings, or reports or unpublished documents from any scientific or medical advisory committee participating in the Boston Fever Study.

**Response to Request No. 25:**

Respondents will provide copies of minutes from meetings of the Advisory Committee to the Boston University Fever Study.

**CONCLUSION**

Petitioners have failed to justify their requests for confidential business information regarding the relationship between Boston University and McNeil or to meet their burden of showing that these and their remaining requests are relevant to the subject matter involved in the instant action. As such, their Motion to Compel should be denied.

Respectfully submitted,

ALLEN A. MITCHELL, SAMUEL M. LESKO,  
TRUSTEES OF BOSTON UNIVERSITY,  
By their attorney,

s/Erika Geetter

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